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IN THE SUPREME COURT OF THE UNITED STATES

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MAYO COLLABORATIVE SERVICES, DBA :

MAYO MEDICAL LABORATORIES, ET AL., :

Petitioners :

v. : No. 10-1150

PROMETHEUS LABORATORIES, INC. :

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Washington, D.C.

Wednesday, December 7, 2011

The above-entitled matter came on for oral
argument before the Supreme Court of the United States
at 10:05 a.m.

APPEARANCES:

STEPHEN M. SHAPIRO, ESQ., Chicago, Illinois; for
Petitioners.

DONALD B. VERRILLI, JR., ESQ., Solicitor General,
Department of Justice, Washington, D.C.; for
United States, as amicus curiae.

RICHARD P. BRESS, ESQ., Washington, D.C.; for
Respondent.

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P R O C E E D I N G S

(10:05 a.m.)

CHIEF JUSTICE ROBERTS: We'll hear argument first this morning in Case 10-1150, Mayo Collaborative Services v. Prometheus Laboratories.

Mr. Shapiro.

ORAL ARGUMENT OF STEPHEN M. SHAPIRO

ON BEHALF OF THE PETITIONERS

MR. SHAPIRO: Thank you, Mr. Chief Justice, and may it please the Court:

We're here today to urge the Court to reinstate the district court's decision, which faithfully applied this Court's precedents under section 101 of the Patent Act. The problem with the Prometheus patent is its broad pre-emption of a physical phenomenon, which prevents others like Mayo Clinic from offering a better metabolite test with more accurate numbers.

And this is a huge practical problem for patients. These thiopurine drugs are strong medicine. Too much of this can be fatal; too little can leave a chronic lingering disease in the patient.

JUSTICE SOTOMAYOR: I'm sorry. I didn't think that this patent covered the actual machine. Mayo is free to develop a new machine.

1 MR. SHAPIRO: Well, it -- what it can't do
2 is use any number from 400 up until infinity, and it
3 believes that's the wrong number. And it can't have a
4 -- a different standard for a legion of autoimmune
5 diseases, and there are dozens and dozens of them.
6 That's a broad field to pre-empt the natural phenomenon.

7 JUSTICE SOTOMAYOR: Well, it -- it actually
8 is much narrower than that. It's within a range, two
9 ranges actually. And so, it has already changed one
10 range, and that's not the subject of the district
11 court's finding that the lower number it's proposing is
12 infringing.

13 So, it's not as broad as you are stating.

14 MR. SHAPIRO: Well, you -- you see, Your
15 Honor, we believe the correct number is 450 to 700. And
16 that's necessary to cure various autoimmune diseases.
17 And Prometheus took the position that its patent
18 pre-empts everything above 400, all the way up to
19 infinity, it said, for all autoimmune diseases, dozens
20 and dozens of them.

21 JUSTICE SOTOMAYOR: Well, it took that
22 position, but the district court narrowed it to 15
23 percent, to 15 --

24 MR. SHAPIRO: Well, you know, actually it
25 didn't, Your Honor. You'll see in that opinion, there

1 are two rulings. One is the 15 percent ruling, which
2 lowers the number; but it said 400 and above all the way
3 to infinity. There's no upper limit on this.

4 So, as a practical matter, there's no room
5 for anybody else to offer a metabolite test. And what
6 this means for patients is one opinion in the United
7 States. If you have one of these life-threatening
8 diseases --

9 JUSTICE SOTOMAYOR: It can offer the test.

10 MR. SHAPIRO: -- you get one opinion.

11 Pardon me?

12 JUSTICE SOTOMAYOR: It can offer the test.

13 It just can't recommend the dosage to the doctor.

14 MR. SHAPIRO: Well, it can't have a test
15 that has a different therapeutic range, because that's a
16 pre-emption. They take the position --

17 JUSTICE SOTOMAYOR: Tests do two things:

18 They measure something --

19 MR. SHAPIRO: Yes.

20 JUSTICE SOTOMAYOR: -- and therapeutic range
21 does something else. The tests can happen. The doctor
22 gets a number. What the doctor does with that number is
23 a different issue.

24 MR. SHAPIRO: And -- and what -- what
25 Prometheus submitted and the court agreed is if you are

1 notified, if you are aware of their range when you're
2 drawing blood, that's an infringement right then and
3 there, if -- if you're aware or warned by their number.

4 So, any doctor in the United States that
5 draws blood and is aware of this range of theirs is
6 pre-empting. And the practical result is we haven't
7 been able to offer this competing test now for 7 years.

8 JUSTICE KENNEDY: When -- when the
9 Respondent addresses this, will they take issue with the
10 way you describe what has been pre-empted, or as you
11 read their -- we'll ask them -- but as you read their
12 brief, is this crystal-clear?

13 MR. SHAPIRO: Well, you'll see,
14 Justice Kennedy, in the district court, they argued for
15 any number above 400. That's -- it's 400 and above, is
16 what it says. And they said there's no upper limit on
17 that. The district court found that. That was their
18 position. It was accepted.

19 JUSTICE KENNEDY: In thinking about what's
20 pre-empted, I looked at the Diehr case involving the
21 rubber molding --

22 MR. SHAPIRO: Yes.

23 JUSTICE KENNEDY: -- and the constant
24 monitoring. And if you could take an analogy from that,
25 let's -- let's suppose that there was a system of

1 measurements that you take every half-hour which
2 constantly monitor how a drug is being retained in the
3 tissues, and that there is a protocol for the admission
4 of some two or three different drugs to get the balance
5 right. In other words, it's much more complicated.

6 Is there some point at which that is
7 patentable, even though this pre-empts a -- a whole
8 range of different choices?

9 MR. SHAPIRO: Well, it may be patentable.

10 JUSTICE KENNEDY: And it's hard for you to
11 answer -- you know, there's a million hypotheticals.
12 But I'm just trying to --

13 MR. SHAPIRO: The key is the specificity.

14 JUSTICE KENNEDY: -- see what the process is
15 here.

16 MR. SHAPIRO: If it leaves room for others
17 to have their own tests with different numbers and
18 different procedures so that it isn't just one test for
19 the whole country, then yes, if it's specific enough.
20 The specificity is the key.

21 What -- what the Court said in *Bilski*, of
22 course, is that you can't pre-empt a whole field, a
23 broad field with -- with your -- your patent, which this
24 one does. And if you look at the diseases that are
25 covered --

1 JUSTICE SCALIA: I -- I'm not comfortable
2 with that. I mean, it depends on how -- how broad it
3 is?

4 MR. SHAPIRO: Yes. If you -- if you
5 pre-empt all the numbers up to infinity and all
6 autoimmune diseases, that's a vast field. It's much
7 bigger than the field in Flook.

8 JUSTICE SCALIA: What about up to 700? Is
9 that okay?

10 MR. SHAPIRO: Well, no. I -- I think --

11 JUSTICE SCALIA: 550?

12 MR. SHAPIRO: No. I -- I think --

13 JUSTICE SCALIA: 830?

14 MR. SHAPIRO: No.

15 JUSTICE SCALIA: I mean, how are we supposed
16 to apply that kind of a rule?

17 MR. SHAPIRO: Well, I think doctors have to
18 have freedom to make their own judgments about these
19 natural phenomena.

20 JUSTICE SCALIA: Above -- above 830 or below
21 830? Which?

22 MR. SHAPIRO: Well, I -- no. I think --

23 JUSTICE SCALIA: It just seems to me not
24 a -- not a patent rule that we could possibly apply.

25 MR. SHAPIRO: Well, it's the rule I believe

1 adopted in Bilski and in Flook, that you can't wipe out
2 a whole field so no one else can have a competing test.
3 The result for the public is that these numbers would be
4 frozen for 20 years, and a very serious person couldn't
5 get a second opinion from Mayo Clinic, which uses
6 different numbers. That's why we think --

7 JUSTICE SCALIA: Doesn't -- doesn't any --
8 any medical patent rely on natural processes? I mean,
9 even if you invent a new drug, what that new drug does
10 is -- is natural. It affects the -- the human
11 physiognomy --

12 MR. SHAPIRO: Oh, yes.

13 JUSTICE SCALIA: -- in a certain natural
14 way.

15 MR. SHAPIRO: Oh, yes.

16 JUSTICE SCALIA: Is it -- is it therefore
17 precluded from patentability?

18 MR. SHAPIRO: No, it's not. And, in fact,
19 this drug was patented.

20 JUSTICE SCALIA: What's different here?

21 MR. SHAPIRO: The difference is the
22 specificity. If you invent a drug which has a
23 particular chemical formula, others can invent other
24 drugs. There's room for competing drugs in the medical
25 world. And you'll -- many, many patented drugs --

1 JUSTICE KENNEDY: I thought your answer to
2 Justice Scalia would be -- and please correct me -- the
3 difference is, is that what the Respondent is claiming
4 is a -- a patent on the measurement of the result.

5 MR. SHAPIRO: Yes, it is a patent on a
6 measurement --

7 JUSTICE KENNEDY: But you're giving a
8 different answer.

9 MR. SHAPIRO: Well --

10 JUSTICE KENNEDY: I mean, that's how I would
11 have answered the question. But that's obviously not --

12 MR. SHAPIRO: No, I --

13 JUSTICE KENNEDY: -- the right way to do it.

14 MR. SHAPIRO: I think that's -- that's
15 one -- one part of it.

16 JUSTICE SCALIA: Well, that's another one of
17 your arguments, but one of your arguments says you can't
18 patent nature.

19 MR. SHAPIRO: You can't patent nature.

20 JUSTICE SCALIA: Right.

21 MR. SHAPIRO: That's correct.

22 JUSTICE SCALIA: And that relates to the
23 question that I asked.

24 MR. SHAPIRO: But --

25 JUSTICE SCALIA: And tell me why you can't

1 patent nature, then?

2 MR. SHAPIRO: Because -- because of the law
3 of nature doctrine that has existed for 150 years in
4 this Court. Congress has never disagreed with that.
5 Pieces of nature can't be monopolized. Neither can
6 formulas.

7 JUSTICE BREYER: Yes. Yes, but your
8 question --

9 JUSTICE KENNEDY: Nature always -- nature
10 always has a reaction to the drug.

11 MR. SHAPIRO: Pardon me?

12 JUSTICE KENNEDY: Nature always has a
13 reaction to the drug.

14 MR. SHAPIRO: Yes. So, all doctors --
15 that's part of the storehouse of information. All
16 doctors can look at that reaction. They can calibrate
17 it the way they see fit. They have different opinions.
18 And it's important for all of us that they have those
19 different opinions. We found that the numbers that they
20 were using were way off for skin disorders, dangerously
21 high. 400 is the wrong number. The correct number is
22 150 to 300.

23 Now, it's very important for patients to
24 be -- with life-threatening conditions, to be able to
25 get that information.

1 JUSTICE BREYER: All right. But then, how
2 do you -- that's -- I see that. I will spare you the
3 reasons why I think the law of nature doctrine exists,
4 because they are not relevant to my question.

5 My question is I think it's hornbook law
6 that the law of nature cannot be patented.

7 MR. SHAPIRO: Yes.

8 JUSTICE BREYER: It is also hornbook law
9 that the application of a law of nature can be patented.

10 MR. SHAPIRO: Right.

11 JUSTICE BREYER: All right. So, in this
12 case, what I think the claim is, is that we are applying
13 a law of nature. Now, we read the words of applying it:
14 Administer a drug, determine the level. And then it
15 uses the word "wherein," which I'll ask them what that
16 means. But -- but -- so, they say those two words,
17 administer the drug, determine the level, are the
18 application of the law of nature that they found.

19 Now, there's something odd about that in
20 your view --

21 MR. SHAPIRO: Yes.

22 JUSTICE BREYER: -- at least. And I want to
23 know what.

24 MR. SHAPIRO: For us, the real oddity is
25 that this numerical calibration that they've given

1 extends up to infinity, and it precludes every other
2 blood test.

3 JUSTICE BREYER: All right. Suppose it
4 didn't. Suppose I discover that if I take aspirin,
5 someone takes aspirin, I discover they have to take
6 aspirin for a headache, and, you know, I see an amazing
7 thing: If you look at a person's little finger, and you
8 notice the color, it shows the aspirin, you need a
9 little more; unless it's a different color, you need a
10 little less. Now, I've discovered a law of nature --

11 MR. SHAPIRO: Yes.

12 JUSTICE BREYER: -- and I may have spent
13 millions on that. And I can't patent that law of
14 nature, but I say I didn't; I said apply it. I said
15 look at his little finger.

16 MR. SHAPIRO: Sure.

17 JUSTICE BREYER: Okay? Is that a good
18 patent or isn't it?

19 MR. SHAPIRO: No, it's -- it's not.

20 JUSTICE BREYER: Why not?

21 MR. SHAPIRO: It's not a good patent
22 because --

23 JUSTICE BREYER: If you can tell me why not,
24 I'll have an understanding of where you're coming from.

25 MR. SHAPIRO: Well, because you've -- you've

1 added to a law of nature just -- just a simple
2 observation of the man's little finger.

3 JUSTICE BREYER: Ah. Now, we're into the
4 problem. And that is the problem of how much you have
5 to add.

6 MR. SHAPIRO: Yes.

7 JUSTICE BREYER: If you look at the Court's
8 cases, they seem to say Flook, one thing, and Diehr,
9 another thing.

10 And so, what is your view about how much has
11 to be added to make it an application of a law of
12 nature? And how would you put that in words?

13 MR. SHAPIRO: There are several things that
14 it can't be. After Bilski, which reaffirmed what was
15 said in Flook, a conventional step isn't sufficient,
16 because that's just adding a law of nature to prior art,
17 and prior art plus prior art equals nothing that is
18 patentable under the Flook decision.

19 And also, the step that you add has to
20 narrow your pre-emption --

21 JUSTICE SCALIA: Excuse me. Does that
22 render it nonpatentable because it's not novel? Is that
23 the reason why it -- it renders it nonpatentable?

24 MR. SHAPIRO: Well --

25 JUSTICE SCALIA: That's not what we're

1 talking about here; we're not talking about novelty, are
2 we?

3 MR. SHAPIRO: No, we're really not. What
4 the Court -- what the Court said in *Bilski* is that a
5 conventional step plus a law of nature isn't sufficient,
6 and what the Court explained in *Flook* is that the law of
7 nature is part of the common domain; it's part of prior
8 art. So, if you're adding prior art to prior art, it's
9 nothing under section 101.

10 JUSTICE GINSBURG: Mr. Shapiro, on that
11 question and the question Justice Scalia just raised,
12 the Government, you know, has taken the position that
13 you're under the wrong section. It's not a question of
14 patentability, but you've used the example of the
15 finger; you said it's obvious. So, why didn't you raise
16 the sections that the Government says would have been
17 the appropriate ones on the novelty or anticipation of
18 prior art and obviousness?

19 MR. SHAPIRO: That's a very important
20 question for the medical community. They need a robust
21 section 101 standard because under 102 and 103 you could
22 patent E equals MC squared. That's new. It's
23 nonobvious. But you can't patent it under 101 because
24 it's a law of nature.

25 And it's important to keep this -- this

1 common domain, the storehouse of information that
2 medical researchers need to have access to --

3 JUSTICE KENNEDY: It's hard to resist the
4 temptation to peek into the obvious component or the
5 nonobvious component and then go back and apply it to
6 101.

7 MR. SHAPIRO: Yes.

8 JUSTICE KENNEDY: You want us to discipline
9 ourselves to talk just about 101 in this.

10 MR. SHAPIRO: Well, no, I think -- we have
11 two arguments on this point. The first is both Flook
12 and Bilski peeked, and -- and they looked at the
13 conventional nature of the additional step, and
14 that's --

15 JUSTICE SCALIA: But once you say
16 "conventional nature," you're saying it's not novel.
17 If -- if the step is not conventional, it's okay. Why?

18 MR. SHAPIRO: Well --

19 JUSTICE SCALIA: Because it's novel.

20 MR. SHAPIRO: This -- this is the Court's
21 101 analysis in both Flook and in Bilski. So, we rely
22 on the latest decision, Bilski, which took exactly that
23 peek. But the other part of our answer is you don't
24 even have to peek. If the step doesn't narrow the
25 pre-emption of the natural phenomenon, if it's just an

1 incidental step that you need to use to observe the
2 natural phenomenon, which this blood test is, you can't
3 see the natural phenomenon.

4 JUSTICE BREYER: You are getting warmer,
5 but --

6 (Laughter.)

7 JUSTICE BREYER: But the -- the words, look,
8 "a simple conventional step." Hmmm. You see, whether
9 it's true in this case or not, discovering natural laws
10 is often a very expensive process.

11 MR. SHAPIRO: Oh, yes.

12 JUSTICE BREYER: And there's lots of
13 investment to be protected.

14 MR. SHAPIRO: Oh, sure.

15 JUSTICE BREYER: But they can't, okay? So,
16 now you're going to say, well, what do they have to add
17 to that? And now we run into problems, because if you
18 have to just not look at the law of nature, don't look
19 at it when you decide whether it's novel, that not only
20 runs into conflict with prior cases, but it doesn't make
21 much sense because really the novel thing is often the
22 law of nature. But you say you have to add something.

23 MR. SHAPIRO: Yes.

24 JUSTICE BREYER: What?

25 MR. SHAPIRO: Our view --

1 JUSTICE BREYER: And now, that's -- what do
2 you have to add? And it can't be that you take the law
3 of nature out and look to whether the rest of it meets
4 the patent criteria. It's -- it's pretty clear in the
5 law, and I can give you reasons why, but forget the
6 reasons.

7 But, look, what do you want to say the rest
8 of it has to add up to?

9 MR. SHAPIRO: In our view, the rest of it
10 has to add up to some step that limits the natural
11 phenomenon, so that you have a concrete, specific --

12 JUSTICE BREYER: You're going on a
13 limitation thing. So, you're going to say reject all
14 the 15 fancy hypotheticals I'll also spare you.

15 MR. SHAPIRO: Well, in the Diehr -- in the
16 Diehr --

17 JUSTICE BREYER: But it's pretty easy to
18 think of the same problem you have, you know, which
19 doesn't have this infinity in it.

20 MR. SHAPIRO: In the Diehr case --

21 JUSTICE BREYER: Which unfortunately we have
22 to deal with.

23 MR. SHAPIRO: In the Diehr case, the natural
24 phenomenon was limited with steps that confined the
25 invention to a specific machine with doors opening and

1 closing, temperature being monitored so a product was
2 cured. It was a very specific, concrete invention.

3 JUSTICE SOTOMAYOR: I -- I don't know
4 what -- you keep saying you have to limit the product.

5 MR. SHAPIRO: Yes.

6 JUSTICE SOTOMAYOR: But you told me that
7 there's a different range for the treatment of skin
8 diseases.

9 MR. SHAPIRO: Yes.

10 JUSTICE SOTOMAYOR: So, presumably, there
11 are different ranges for treatment of other diseases.

12 MR. SHAPIRO: Absolutely.

13 JUSTICE SOTOMAYOR: So, this patent has not
14 limited exploration in there. You're claiming it has.
15 That's an issue that your adversary can speak to. I
16 think they say no in their briefs.

17 But the point is there's still a limit to
18 their range. You're claiming at one point they said it
19 was limitless, but if we disagree with that --

20 MR. SHAPIRO: Well, here's what --

21 JUSTICE SOTOMAYOR: -- how do you answer
22 Justice Breyer's question?

23 MR. SHAPIRO: Here's what they say, joint
24 appendix pages 13 through 14, the second volume. This
25 is their patent. This is what it covers. It covers

1 hepatitis, lupus, Hashimoto's disease, Graves' disease,
2 Addison's disease, diabetes, arthritis. And they say it
3 even covers organ transplants. It covers heart, kidney,
4 and liver transplants. So, it covers every autoimmune
5 disease, and there are dozens and dozens of them --

6 JUSTICE KAGAN: Mr. Shapiro --

7 MR. SHAPIRO: -- and they do have different
8 numbers. That's the key point.

9 JUSTICE SOTOMAYOR: So, do we -- do we add
10 up all of the diseases in the world, all the potential
11 diseases, and pick a percentage that this covers within
12 that range?

13 MR. SHAPIRO: Well, this --

14 JUSTICE SOTOMAYOR: I think Justice Breyer
15 is asking you for something that doesn't involve that --

16 MR. SHAPIRO: Well --

17 JUSTICE SOTOMAYOR: -- that involves some
18 greater answer to the issue of limitation.

19 MR. SHAPIRO: I -- I think what the Court
20 did in Flook and what it did in Bilski is ask if a broad
21 field is being pre-empted. This is broad numerically.
22 It goes up to infinity. It covers dozens and dozens of
23 autoimmune diseases.

24 JUSTICE SCALIA: What if -- what if you --
25 what if they just split up the patent? They -- they got

1 one patent number for arthritis, another patent number
2 for transplants, another patent number for each one of
3 the autoimmune diseases you're talking about?

4 MR. SHAPIRO: Well --

5 JUSTICE SCALIA: Would each of them be okay,
6 because it's --

7 MR. SHAPIRO: No, it wouldn't. That would
8 be LabCorp, where there was just one malady in the
9 patent; it was a vitamin deficiency with a natural
10 correlation. And Justice Breyer's opinion explained
11 that -- that is too pre-emptive of the natural
12 phenomenon.

13 JUSTICE BREYER: Yes, but what my opinion
14 lacked, frankly, and that's sometimes the virtue of a
15 dissent in such a case, it lacked -- and Novartis points
16 this out very well in their brief -- it lacked an
17 explanation as to why what I thought was a patent just
18 said observe the correlation.

19 MR. SHAPIRO: Yes.

20 JUSTICE BREYER: Why isn't that an
21 application of the law of nature? And if you look to
22 LabCorp's dissent to find an answer to that question,
23 you're better than I, because I couldn't find it.

24 MR. SHAPIRO: Well, if -- if observe the --
25 that's another area of the breadth of this patent,

1 because there's no specific action the doctor has to
2 take. If the doctor has been informed of their range
3 and draws blood and thinks about it, that's -- that
4 is -- that is infringement. And a doctor here was
5 accused of infringement, treble damages sought against
6 this hospital in an injunction, because she thought
7 about this correlation, and she had completely different
8 numbers.

9 JUSTICE KAGAN: Is there -- Mr. Shapiro, is
10 there a patent that Prometheus could have written that
11 you think would have met the 101 test?

12 MR. SHAPIRO: Certainly. They could have
13 said when you reach 400, a real number, a specific
14 number, you adjust the dosage by 20 percent. That's a
15 treatment patent.

16 JUSTICE KAGAN: So, if they had added a
17 treatment protocol, that would have been a completely
18 different case?

19 MR. SHAPIRO: Yes, and --

20 JUSTICE KAGAN: And what makes it a
21 completely different case?

22 MR. SHAPIRO: What makes it different is
23 that leaves room for Mayo Clinic to come up with
24 different numbers that it believes are more accurate and
25 more helpful for patients that are suffering from these

1 life-threatening diseases. We shouldn't require
2 Americans to get one opinion from Prometheus when they
3 want an opinion from Mayo Clinic.

4 JUSTICE KAGAN: Well, I guess I'm not sure I
5 understand that. You said a specific number. But
6 suppose it uses ranges, but it also attaches treatment
7 decisions to those ranges.

8 MR. SHAPIRO: Well, that could be specific
9 enough, again, then others could have a rival test that
10 -- that used a different treatment protocol. You'd have
11 to look at that.

12 JUSTICE KAGAN: So, if the idea --

13 JUSTICE KENNEDY: Well, then why -- then why
14 didn't you answer her first question that it was -- that
15 it was not patentable? I have the same --

16 MR. SHAPIRO: Oh, I think --

17 JUSTICE KENNEDY: I think I'm having the
18 same trouble as Justice Kagan.

19 MR. SHAPIRO: I think it would be
20 patentable.

21 JUSTICE KENNEDY: Why can't you just go --
22 the hypothetical was -- was one range, one result.
23 Pardon me. One measurement, one result. Suppose that
24 just continued over a range. And they said if it's 40,
25 then you have this; if it's 50, you have this.

1 MR. SHAPIRO: Well, I don't think they
2 can -- they can wipe out the entire field so that others
3 can't have rival tests that use different numbers. They
4 tried to do that, by the way. They have a total of
5 eight patents here which use different numbers. But you
6 can't pre-empt the whole field so others can't make any
7 use of the natural phenomenon.

8 JUSTICE KAGAN: I guess the question -- the
9 question I'm asking is, in your response to me, is the
10 difference the -- the extent of the ranges, or is the
11 difference that there would be clear treatment decisions
12 attached to those ranges?

13 MR. SHAPIRO: I think you'd need both.
14 You'd have to look at it in practical terms. Is there
15 room for somebody else to make use of this natural
16 correlation, so that they could come up with different
17 numbers, different ranges, and different treatments?
18 And if there's room left, then there is no pre-emption
19 of the natural phenomenon. That's a vastly different
20 case, and that's what is missing here. I -- I do see my
21 time -- yes?

22 JUSTICE SOTOMAYOR: How many patents of this
23 type are out there?

24 MR. SHAPIRO: My view is there are only a
25 couple of them. LabCorp is like this. This one is like

1 this. The others that are referred to in this -- these
2 amicus briefs are vastly different. They're specific
3 patents with specific treatment protocols. And by the
4 way, the Government admits this particular patent is
5 invalid because it just attaches a mental step to prior
6 art. And there are only a couple of them to our
7 knowledge that would be affected by a decision in our
8 favor.

9 But a decision in our favor would protect
10 the storehouse of information that doctors really need.
11 They have to be able to look at the body's reaction to
12 injections, pills, chemotherapy, radiation; and
13 different hospitals have to have different opinions to
14 safeguard the health of our people.

15 So, we urge the Court to reverse, and I
16 would reserve the balance of our time.

17 CHIEF JUSTICE ROBERTS: Thank you, counsel.
18 General Verrilli.

19 ORAL ARGUMENT OF DONALD B. VERRILLI, JR.,
20 ON BEHALF OF THE UNITED STATES,
21 AS AMICUS CURIAE

22 GENERAL VERRILLI: Mr. Chief Justice, and
23 may it please the Court:

24 Each party in this case has got a valid
25 point. Mayo is correct that you can't get a patent by

1 tacking a mental step onto an utterly conventional
2 process for administering drugs and testing their
3 effects. But that is an issue under sections 102 and
4 103 of the Patent Act.

5 JUSTICE GINSBURG: Mr. Shapiro just told us,
6 when I asked him that question based on your -- your
7 brief, that people need to know up front that it's --
8 this is not a patentable subject matter; very important
9 that it be 101 and not 102 and 103. So, how do you
10 answer his rejection of the adequacy of prior --
11 anticipating prior art or obviousness?

12 GENERAL VERRILLI: I think the answer,
13 Justice Ginsburg, is that from the perspective of the
14 United States and the PTO, it's exactly the opposite;
15 that importing these -- taking -- as Justice Kennedy
16 suggested, taking up the temptation to import a look
17 into novelty and nonobviousness into the 101 inquiry is
18 going to be very destabilizing; that 101, as Bilski
19 said, is a threshold eligibility test, and the question
20 is whether there is a process.

21 Here there is a process. It's the
22 administration of a drug that changes the body
23 chemistry, and there's then a test to determine the
24 extent of the change, and then there's an inference at
25 end of the test. That's a process.

1 CHIEF JUSTICE ROBERTS: That -- in your test
2 for that -- I see on page 9 of your brief you say: "a
3 classic patent-eligible process," "recites a series of
4 acts, performed in the physical world, that transforms
5 the subject of the process ... to achieve a useful
6 result." So, I have a great idea. You take wood, you
7 put it on a grate, you light it, and you've got heat.
8 That is -- recites a series of acts performed in the
9 physical world that transforms the subject of the
10 process, the wood, to achieve a useful result, which is
11 heat. So, I can get a patent for that?

12 GENERAL VERRILLI: No. It's not novel, and
13 -- and it's obvious.

14 CHIEF JUSTICE ROBERTS: No, no, no. No.
15 Well, let me put it --

16 GENERAL VERRILLI: You can't get a patent
17 for it.

18 CHIEF JUSTICE ROBERTS: That's patent --
19 that's patent- eligible.

20 GENERAL VERRILLI: But that's our -- that's
21 our point, Mr. Chief Justice, that the -- that the right
22 way to look at this issue is under 102 and under 103.
23 And I think --

24 JUSTICE BREYER: Why? Why is the question.

25 GENERAL VERRILLI: Because --

1 JUSTICE BREYER: Look, anything can be
2 transformed into a process. Look at those real estate
3 ones, the -- I mean, you know, lawyers ones. I have a
4 way of making a great argument in the Supreme Court.
5 You know, you could patent some of your arguments.

6 (Laughter.)

7 GENERAL VERRILLI: Most are pretty obvious.

8 JUSTICE BREYER: Why not cut them off at the
9 pass? That is, if you're really prepared to say -- it
10 has to do with process, not machines. In the 19th
11 century, not many patent processes were granted. So,
12 they're rather special because of the special problem
13 the Chief just noticed. So, why not --

14 GENERAL VERRILLI: Well, here's -- here's --

15 JUSTICE BREYER: -- cut them off at the
16 pass, if you're prepared to say --

17 GENERAL VERRILLI: I'm sorry.

18 JUSTICE BREYER: Well, I'll add a little bit
19 to this because I am questioning what you say here in
20 the other direction. You say if you just look at
21 everything minus the law of nature, hmm, and that is a
22 process that's otherwise known or obvious in light of
23 the prior art, you can't patent it. That seems to me
24 maybe it goes too far the other direction, because we
25 know that a lot of work goes into these laws of nature.

1 GENERAL VERRILLI: But our position is a
2 little different.

3 JUSTICE BREYER: Yes, but I -- all right.
4 So, there are both parts, but I'm more interested in --

5 GENERAL VERRILLI: Your Honor, if I could --
6 if I could, I do think that one has to think about if --
7 what -- this seems like a straightforward case on these
8 facts, but if one thinks about the principles that Mayo
9 is advocating and applying them in a different set of
10 circumstances, I think you'll see the problems.

11 Take, for example, nuclear stress tests that
12 cardiologists use. That's a process. The patient gets
13 on a treadmill. The heart rate gets elevated.
14 Radioactive dye gets put into the body. It allows an
15 image to be taken of the heart with an X-ray machine.
16 That improves treatment. Now, the transformation there
17 is, as in this case, incidental to the process. It's
18 not the point of the process. But I don't think anyone
19 would suggest that that's not a patentable process, but
20 under Mayo's test, it's not a patentable process.

21 Similarly, I think -- I'm sorry,
22 Mr. Chief Justice.

23 CHIEF JUSTICE ROBERTS: I was just going to
24 say, what is the great advantage you see of putting this
25 critical question off until the 102, 103 analysis,

1 rather than cutting it off at the beginning, 101, which
2 I understand your friend to say is very important
3 because you don't want people to have to pause terribly
4 long to see if this is something they can -- can do?

5 GENERAL VERRILLI: As a practical matter, at
6 the PTO, Mr. Chief Justice, it doesn't make any
7 difference, because the PTO examiner gets a patent
8 application and answers every question, 101, 102, 103,
9 112, and makes a decision about all of them. So, it's
10 not going to lead to any benefit at the PTO.

11 CHIEF JUSTICE ROBERTS: What about -- what
12 about litigation? Is it -- it is easier to throw
13 something out at the threshold level, isn't it, than to
14 move further down the line?

15 GENERAL VERRILLI: Not -- not if one moves
16 the novelty and the obviousness inquiries from 102 and
17 103 into 101. You've just taken --

18 JUSTICE KENNEDY: Well, I'm not so sure.

19 GENERAL VERRILLI: -- the complexity of 102
20 and 103 and moved it into 101.

21 JUSTICE KENNEDY: We're talking about
22 summary judgment. It seems to me, rough rule, that
23 summary judgment would be much more -- much easier under
24 101 than 102 and 103.

25 GENERAL VERRILLI: I think this case is a

1 pretty good illustration, Justice Kennedy, of why that's
2 not true. Think of -- if I may pick up on the question
3 Justice Scalia asked my friend, think of all the trouble
4 we're having in this case figuring out what the standard
5 is: How much pre-emption is too much? How do you even
6 figure out the scope of pre-emption? What you're
7 actually doing here is multiplying a whole new set of
8 very difficult, complex questions that you don't have to
9 answer if --

10 JUSTICE KAGAN: But, General, I read you in
11 part as saying don't worry, because if something strikes
12 you as wrong with this patent, we're going to catch it
13 under 102. And I guess I'm not sure why that's true.
14 There was novelty here. There were some doctors who
15 figured out some new things, which was new ranges of
16 effective drug treatment. And so, why do you think
17 you're going to catch this as a 102 matter? If there is
18 a problem here, it seems to me not the fact that there
19 was something new. There was something new. It's
20 that -- it's something else.

21 GENERAL VERRILLI: But there was no new
22 process, Justice Kagan. There's exactly the same
23 process that already exists, with a new inference drawn
24 at the end, and that's why you can capture this under
25 102.

1 And I do think it's important to think about
2 it in terms of the points Mr. Shapiro is making. If
3 this patent had involved -- instead of standard old
4 blood tests, had involved a breakthrough new test that
5 allowed one to measure metabolite levels in a way that
6 could never have been done before, of course the person
7 who invented that could get this patent, even though it
8 would have the excluding effect that Mr. Shapiro has
9 identified.

10 Similarly, if the drug is a breakthrough
11 drug and a patentable drug, any use of the drug during
12 its patented period, including a use in a test like
13 this, would be an infringement under 271.

14 JUSTICE SCALIA: What about the --

15 JUSTICE ALITO: Can I ask you about your --

16 CHIEF JUSTICE ROBERTS: Justice Scalia.

17 JUSTICE SCALIA: What about the discovery of
18 a new physical change in the body caused by an old drug?
19 You -- you find that it affects another part of the
20 human system. Is it -- is that discovery patentable?

21 GENERAL VERRILLI: Well, I think that's a
22 harder question, but there are, for example -- and I
23 think the Court was looking at some of this in the
24 Caraco case on Monday -- these follow-on patents with
25 respect to pharmaceutical products, where you patent it

1 originally for one use, and then you can later patent it
2 when you discover a different use. And, in fact,
3 there's an entire regulatory system set up to deal with
4 that. So, I do think there are circumstances in which
5 that can be patentable, yes.

6 JUSTICE ALITO: Could I ask you about your
7 argument that the correlations that were discovered and
8 that are involved here are not natural phenomena because
9 the thiopurine drugs are synthetic products of human
10 ingenuity? I found that a little difficult to
11 understand.

12 Suppose someone discovers the level at which
13 a human pollutant that's present in the atmosphere, in
14 the air or the water, has an adverse effect on human
15 health. Is that not a natural phenomenon?

16 GENERAL VERRILLI: The existence of a
17 pollutant in the air and its effect probably is a
18 natural phenomenon, but the difference here is that
19 there's a conversion of the natural body chemistry. The
20 metabolites wouldn't be in the body but for the
21 administration of these drugs.

22 And I do think if one were to say that
23 that's an unpatentable natural phenomenon -- and this is
24 what I mean about the destabilizing risk of thinking
25 about this as a 101 issue rather than 102 or 103 --

1 you're going to call into question lots and lots,
2 thousands in fact, of medical use patents where the
3 patent is administer a therapeutically effective dosage
4 of this drug in order to treat this disease.

5 JUSTICE BREYER: Yes, but this drug is
6 patentable because it's a -- it's a -- what is the third
7 word? You know, it's a combination of nature. What's
8 the -- it's a composition of matter.

9 GENERAL VERRILLI: Yes, Justice Breyer, but
10 those patents are not on the composition of matter.

11 JUSTICE BREYER: No, they don't have to be.

12 GENERAL VERRILLI: Those are process
13 patents.

14 JUSTICE BREYER: You'd say -- you would say
15 that where it's a new use there were some
16 specifications, and the specifications limited the area
17 to over here, I think -- and tell me if I'm wrong
18 because I'm really asking just a question. They limit
19 it over here, you see. And now we have a new use, and
20 we're saying this composition of matter is being used
21 over here. So, aren't you getting a -- simply a
22 different area where you're using a composition of
23 matter.

24 GENERAL VERRILLI: Well, but that's a use
25 patent. That's not a composition-of-matter patent

1 and --

2 JUSTICE BREYER: That isn't a process
3 patent.

4 GENERAL VERRILLI: Yes, it's a process
5 patent.

6 JUSTICE BREYER: Is a process --

7 GENERAL VERRILLI: It is a process patent,
8 and the problem would be if one says --

9 JUSTICE BREYER: All right. I'll think
10 about it.

11 CHIEF JUSTICE ROBERTS: Finish your
12 sentence.

13 GENERAL VERRILLI: If one says that it's --
14 it's nonpatentable because all you're doing is patenting
15 the application of a law of nature, you're invalidating
16 all those process patents.

17 Thank you.

18 CHIEF JUSTICE ROBERTS: Thank you, General.

19 Mr. Bress.

20 ORAL ARGUMENT OF RICHARD P. BRESS

21 ON BEHALF OF THE RESPONDENT

22 MR. BRESS: Mr. Chief Justice, and may it
23 please the Court:

24 I'd like to start out, I think, with a --
25 answering the question about what these patents cover

1 and what they don't. And I'm going to answer that
2 really not because I think it has any relevance to the
3 101 issue. I actually don't think it has any relevance
4 to 101. And I'll explain that it does perhaps have
5 relevance under 102 or 103 and why the difference
6 matters, if I may.

7 So, the district -- my friend is correct
8 that in the district court at the initial infringement
9 stage, before the court decided validity of the patent,
10 we argued that the right way to look at our numbers was
11 that we were claiming that if a doctor correlated or
12 associated a number greater than 400 with toxicity --
13 that's what we were claiming. That would be within our
14 claim. And if the doctor correlated under 230 with not
15 enough drug, well, we were claiming that as well.

16 Now, the district court agreed with that and
17 said that those were the ranges. But then it confused
18 things a bit, and that's where we get to the 15 percent
19 plus or minus point. The court also said -- and by the
20 way, I think this is a correct reading -- that when we
21 said about 400, that means plus or minus 15 percent of
22 400, and about 230 plus or minus 230.

23 And then the court held that there was
24 infringement, but it held it for two different reasons.
25 It said that -- that the patent for Mayo -- or the --

1 sorry -- not the patent, the product Mayo had, which, by
2 the way, was awfully close -- it was 235 to 450 -- fell
3 within the 15 percent on the top side. It didn't look
4 at the bottom side for purposes of this decision. But
5 450 was within 15 percent of 400. And it also said it
6 violated it because 450 is greater than 400.

7 At the court of appeals, we argued that the
8 right way to read the district court's opinion was that
9 you had to actually do that comparison, that the ranges,
10 the 15 percents, mattered and that the doctor, in order
11 to infringe, would have to look at the result and say is
12 this or isn't this greater than 400, and compare it to
13 400, or 230.

14 The court of appeals accepted that reading
15 of it, and that reading wasn't disputed by Mayo and, on
16 page 3a of the court of appeals' opinion, the court of
17 appeals says has to be compared to a predetermined
18 number.

19 I think you could go either way on this. I
20 think, frankly, the Court could go back to the district
21 court and look at that, perhaps. But the problem with
22 that is that there was no objection at the court of
23 appeals. And I think any objection to how the court of
24 appeals understood it is probably waived at this point.

25 Now for why it doesn't matter. If there's a

1 problem with the broad ranges here, in other words if
2 there is a problem with the fact that we're saying over
3 400 indicates toxicity, let's think about what is that
4 problem. Suppose we're right. I mean, at this stage,
5 the Court certainly can't presume we're wrong in that.
6 So, let's suppose that we're right. If we're right,
7 then we're simply claiming the fact that we found, that
8 after you administer the drugs and determine the
9 metabolite level, if it's over 400, it indicates
10 toxicity.

11 JUSTICE ALITO: And that's a natural
12 phenomenon.

13 MR. BRESS: It is a -- it's according to a
14 law of nature, and I will agree with that, Your Honor.
15 The term "natural phenomenon" as this Court has used it,
16 for instance, in Chakrabarty or in J.E.M., has referred
17 to the difference between things that exist in nature
18 with the intervention of man and things that exist
19 without the intervention of man. So, for example,
20 photosynthesis would be a process that is a natural
21 phenomenon. On the other hand, cross-breeding plants to
22 create a new variety, that wasn't a natural phenomenon.

23 JUSTICE ALITO: Yes, but if photosynthesis
24 is induced by a lamp inside a building, then it's not a
25 natural phenomenon?

1 MR. BRESS: If it -- I think you could
2 probably get a patent. I think you could get a patent,
3 Your Honor, on the use of a lamp to induce
4 photosynthesis, but you couldn't claim the underlying
5 process, is all I'm saying, of photosynthesis.
6 According to this Court's --

7 JUSTICE BREYER: I thought of two examples
8 that will try to get you to talk about the problem
9 that's really bothering me here, anyway.

10 MR. BRESS: I'd love to, Your Honor.

11 JUSTICE BREYER: Well. A patent for --
12 we've discovered, at some expense, what counts as too
13 little fertilizer and what counts as too much to make
14 plants grow, a certain kind of fertilizer, very common.
15 Less than an quarter of an inch, forget it; more than
16 half an inch, you're going to burn the plant. Imagine
17 that. Law of nature, absolutely, about the chemicals in
18 the fertilizer. Patent: A method for determining when
19 there's too little or too much fertilizer. Put some
20 fertilizer in a field and measure how much there is,
21 wherein less than a quarter of an inch is too little and
22 wherein more than half an inch is too much.

23 Second example. Einstein never lived, but
24 at a vast expense, you invented E equals MC squared,
25 okay, a method for measuring energy which is very useful

1 that comes out of a cyclotron. Put some stuff in a
2 cyclotron, measure the stuff in and measure how much it
3 comes out, and keep -- wherein -- wherein the missing
4 part is -- think about -- wherein -- no, it says wherein
5 the missing part will be calculated as an amount of
6 energy according to a formula E equals MC squared. Yes.

7 If your patent is valid, why aren't the two
8 I just mentioned?

9 MR. BRESS: Okay.

10 JUSTICE BREYER: And if you -- if the two I
11 just mentioned are valid, there is something wrong with
12 this picture.

13 MR. BRESS: Okay, You Honor. I'll answer
14 them in turn, and then hopefully I'll get back to my
15 range and explain what the 102, 103 problems are with
16 that for you all as well.

17 The first patent you've discussed, which is
18 how best to use fertilizer essentially for plants.
19 Patent-eligible subject matter, but clearly novel and
20 novel in a way that you could get rid of on summary
21 judgment just as fast as you could get rid of it on 101.
22 There's no advantage, in other words, to saying I'm
23 going to label my summary judgment motion 101 and import
24 lack of novelty into that versus saying I'm going to
25 label --

1 JUSTICE BREYER: Where is -- where is lack
2 of novelty? Nobody has these numbers before. They
3 always thought it was a quarter, an eighth of an inch,
4 and -- it's huge novelty.

5 MR. BRESS: Your Honor, the law, as you well
6 know, recognizes that under section 103, if something
7 would have been obvious to someone with ordinary skill
8 in the art --

9 JUSTICE BREYER: I mean, my point --

10 MR. BRESS: -- it would fall under
11 obviousness.

12 JUSTICE BREYER: Assume with me the eighth
13 versus quarter of an inch, which is the law of nature
14 part, is not obvious.

15 MR. BRESS: Your Honor, the first person who
16 came up 10,000 years ago with the best way to do -- to
17 use fertilizer in a way that nobody had ever done before
18 would presumably get it. If your question is at what
19 level of sort of microns you can draw the line between
20 obviousness and novelty, those are -- there are
21 questions of fact embedded in that.

22 JUSTICE BREYER: No, no. My question is,
23 what has to be added to a law of nature to make it a
24 patentable process?

25 MR. BRESS: To make --

1 JUSTICE BREYER: And if you put too little
2 in the answer to that question, I believe I can take
3 things like E equals MC squared and make them
4 patentable.

5 MR. BRESS: Okay. Well --

6 JUSTICE BREYER: And if you put too much in,
7 you're going to wreck your own case. So, I'm very
8 interested in hearing --

9 MR. BRESS: Your Honor, I will --

10 (Laughter.)

11 MR. BRESS: I will try very hard not to do
12 either. Your Honor, this Court has looked at two
13 different ways to try to limit what are laws of nature,
14 abstract ideas, et cetera. One way it has looked at is
15 to say we need something physical; it has to be in the
16 world. In other words, you have to move things, you've
17 got to transform them, you have to apply machinery to
18 them, that sort of thing. So, we just know off the bat
19 you're not literally claiming just a principle in the
20 air.

21 So, in your example, if you used, you know,
22 machines, implements, et cetera, to do it, at least we'd
23 know that much. I think the problem that Your Honor is
24 raising is more in the second stage, which is, okay, it
25 isn't just a mere principle. I get that. But are we as

1 a practical matter pre-empting an abstract idea in such
2 a way that we are going to too greatly suppress
3 follow-on invention. And the classic example of that,
4 Your Honor, is the Morse case, of course.

5 In Morse, there were two different claims
6 that were being discussed, actually eight different
7 claims being discussed. But one of the claims had to do
8 with the actual invention of how you can make a
9 telegraph work. And Morse described a working telegraph
10 system, and he got a patent for that.

11 And the second one that he tried to claim
12 was the use of electricity to write at a distance. And
13 the reason he didn't get that one is that it was
14 expressed at such a level -- high level of abstraction,
15 that it would pre-empt many, many things that he had
16 never invented and never thought of. In fact, the
17 Court's words were wonderful in that case: For aught we
18 now know, the Court said, somebody may come up with
19 wonderful inventions in the future. And, of course, now
20 we have the fax machine, e-mail, et cetera.

21 That's the right way to think about it,
22 which is, is the -- for the second step, which is, is
23 what's being claimed at such a high level of generality
24 that it's going to inhibit future innovation.

25 JUSTICE KENNEDY: Why couldn't someone come

1 up with the idea that at a level which is in the range
2 that's within your patent, if at a certain level for a
3 certain -- a person of a certain age, you administer a
4 new drug, you have a new result? Why isn't that like
5 the fax machine?

6 MR. BRESS: Your Honor, in that case, they
7 could get an improvement patent on it, first of all, no
8 question about it, that they could apply for an
9 improvement patent.

10 JUSTICE KENNEDY: But the --

11 MR. BRESS: They're building on it.

12 JUSTICE KENNEDY: -- Petitioner is saying
13 that if you think about that, it's an infringement.

14 MR. BRESS: Well, there's a -- let me
15 explain why I think there's not a problem with that,
16 Your Honor. If you looked at the process for
17 vulcanizing rubber, which Firestone patented many, many
18 years ago, that involved you heat India rubber to a high
19 temperature, you add sulfur and mineral salts, and that
20 way you cure rubber into a usable way of using it.

21 Now, many years later in Diehr, this Court
22 looked at a -- an improved process, if you will, for
23 making rubber which -- which involved continuous
24 measurement and the use of the Arrhenius equation to
25 know when the rubber was cured. Now, there's no doubt

1 that if somebody came out with a second one 10 years
2 after Firestone had gotten the patent on -- on
3 vulcanization, they would have had to pay patent
4 royalties for 10 years before their second one would
5 have been free of patent royalties, right, because they
6 would have had to respect the patent that Firestone got.

7 So, the simple fact, in other words, that
8 there may be further improvements to what you've done
9 isn't where the Court has ever drawn the line. And I do
10 think that in conceptualizing where to draw these
11 lines -- because at the edges they're indeterminate,
12 they're elusive, and you're going to be somewhat
13 arbitrary. This is judge-made law. I think that what
14 you've got to look to is what you've done before.

15 And if we take this case in the spectrum of
16 what this Court has looked at, where you've got Morse on
17 one side, on that same side you've got Benson, which was
18 simply a formula for converting binary coded decimals to
19 pure binary, which the Court said you could use for an
20 infinite number of uses. It was way too broad.

21 If you look at Bilski, a general way of -- a
22 general -- the concept of hedging. Now, Bilski was
23 limited, admittedly, and this Court discussed it and
24 said, well, they've tried to limit it with the
25 conventional step of having the inputs determined by

1 random analysis techniques. I'd like to focus on that
2 for a second, because the Court said that was not
3 significant extra solution activity. It wasn't enough
4 to either render the process a physical one in the world
5 or to narrow its scope. Well, why is that? Because
6 random analysis techniques are themselves just an
7 abstract idea. So, you were adding one abstract idea to
8 another one, and it's no wonder the Court found that it
9 didn't narrow it to a patentable scope.

10 Now, on the other side of the line, we've
11 cases *Tilghman*. Now, if you look at *Tilghman*, *Tilghman*
12 was a patent on the fact that if you use water at a high
13 heat and high pressure, you can separate out from fat
14 bodies the fatty acids, on the one hand, and the
15 glycerin, on the other. And this Court approved a -- a
16 patent process on that. Now, that's of course a natural
17 law, Justice Alito, no question about it, in terms of is
18 it a law of nature that makes you do that? Yes.

19 But the Court was comforted in that case by
20 the fact that the patent wasn't trying to generally
21 patent -- monopolize the idea that water at high
22 pressure and temperature is going to in general break
23 bonds of chemicals. And it wasn't trying to either
24 monopolize the whole idea of how you can separate fat
25 acids and glycerin from fat bodies. There are other

1 ways, including the use of sulfuric acid.

2 Let's place this case in the continuum.

3 Now, we're not trying to patent the general broad idea
4 that you can use metabolite readings after you've
5 administered a drug to determine what the likely -- what
6 the best level of the next administration might be.
7 That would be kind of like the Morse patent, and that's
8 not what we're doing. What we're talking about here is
9 (a) a very specific class of drugs, the thiopurines,
10 used for --

11 JUSTICE KAGAN: But, Mr. Bress, here's what
12 you have not done. What you haven't done is say at a
13 certain number, you should use a certain treatment; at
14 another number, you should use another treatment. So, I
15 guess the first question is, why didn't you file a
16 patent like that? Because that clearly would have been
17 patentable. Everybody agrees with that.

18 MR. BRESS: I agree it would, Your Honor.
19 Two responses if I may.

20 JUSTICE KAGAN: And I think that the
21 difference people are noting or some people are noting
22 is that this is not a treatment protocol. It's not a
23 treatment regimen. All you have done is pointed out a
24 set of facts that exist in the world, that exist in the
25 world, and are claiming protection for something that

1 anybody can try to make use of in any way. And you're
2 saying you have to pay us.

3 MR. BRESS: Your Honor, I don't agree with
4 that description, but let me explain why.

5 JUSTICE KAGAN: I thought you might not.

6 (Laughter.)

7 MR. BRESS: All right, Your Honor, first of
8 all, the -- most of the claims here have three steps.
9 So, you've got an administering step which clearly
10 carries its own benefits with it. It's not -- it's not
11 novel, but it's certainly a process step and in and of
12 itself could be a process. We couple that with
13 determining -- you determine the amount of metabolites,
14 and the next step gives the doctor valuable information
15 in order to decide what to do next.

16 Now, why didn't we say, if it's over 400,
17 you must decrease? Because that doesn't correspond with
18 how doctors practice medicine, Your Honor. So, for
19 example, you've got a patient for whom you've got a
20 particularly sharp outbreak of Crohn's disease. You may
21 well be willing to go above the normal 400 level if your
22 other tests, your liver toxicities, your white blood
23 cell counts, et cetera, tell you that for this patient
24 at this time, given that condition, I'm willing to risk
25 some additional toxicity.

1 On the lower end of the scale, you might
2 have somebody under 230 who seems to be improving. They
3 seem to be moving towards remission. Why push it? Why
4 increase? And this is not unusual. And that's one of
5 the things I think I've got to stress here, is the
6 notion of a patent only in the end producing information
7 is old in this country. And, by the way, to produce the
8 information you're always going to have a step at the
9 end that is some kind of an algorithm. Might be a very
10 simple one but that takes the data, the raw data, and
11 turns it into something useful.

12 So, for example, in the 19th century, there
13 were patents on the use of electricity to locate veins
14 of -- of ore and valuable minerals in the ground. Now,
15 that patent didn't say after you found it, you've got to
16 dig it out. And according to Mayo, that would have to
17 be the next step. But, of course, you might have
18 reasons for digging it out or not digging it out
19 depending on your finances, depending how deep it is,
20 depending on what kind of ore it is, et cetera.

21 There were patents on how to navigate your
22 boat in the fog. It was a primitive sonar-based method.
23 And it didn't tell you in the end, you must steer your
24 boat to X and go there. It just told you a likely way
25 to go. There was not --

1 JUSTICE BREYER: What about a process that
2 all the steps are -- it's a process to -- to generate
3 some useful information.

4 MR. BRESS: Yes.

5 JUSTICE BREYER: All right? Fine. And the
6 only new thing about it is the useful information.
7 Anything like that in history, any patent case that you
8 can -- that comes to mind that you say that was okay?
9 Can you think of one?

10 MR. BRESS: Actually, Your Honor, yes.

11 JUSTICE BREYER: What? Good. That's what I
12 would like to know.

13 MR. BRESS: Certainly. For example, there
14 was a patent on the -- and I can talk about modern ones
15 too, of course, but there was a patent on how to find
16 the -- where there is a leak in a water main, and it was
17 using vibration of the -- of the --

18 JUSTICE BREYER: No, no. That's not what
19 I'm thinking of. I'm thinking of a patent to find
20 useful information that chickens can only eat so much
21 chicken food. That nobody has ever known before, you
22 know. Okay. Now -- or something like that. But they
23 tell you the useful information that's going to be found
24 right in the patent. In other words, we have a patent
25 to discover some useful information, and here is the

1 useful information, and now here's -- see, this is what
2 their complaint is.

3 MR. BRESS: I'm not sure that I'm
4 understanding, Your Honor, because the patent that tells
5 you where to find the ore is telling you what you're
6 going to find.

7 JUSTICE BREYER: But you don't know what
8 you're going to find because you don't know how much ore
9 you're going to find? Let's see. Okay. Let me think
10 about it. Thank you.

11 MR. BRESS: Well -- and if we talk about
12 modern days, because I think it's helpful now to move
13 this forward, the Court has never suggested that there's
14 an extra statutory limitation that prevents patents on
15 developing useful information, even if they have a
16 mental step at the end. And what would -- what do we
17 have today? We've got inventions out there that,
18 through identification of biomarkers or measuring the
19 biomarkers, allow us to know which of 10 particular
20 cancer drugs is going to work for a particular patient.

21 We've got patents on methods that allow us
22 to identify the likely location and size of the next
23 earthquake in the San Andreas fault. We've got patents
24 that allow us to determine where there is a crack and
25 what type of crack in a nuclear reactor core.

1 Now, according to Mayo, because all of these
2 patents end with a mental step that produces
3 information, they're no good. Or, perhaps, if you look
4 at them and say everything up to that algorithm at the
5 end is old, you can't get a patent because you lack
6 novelty.

7 Now, it may be to -- it may be in fact,
8 depending on the particular invention, that you should
9 lose for lack of novelty on one or other of those, or
10 that you should lose for lack -- for obviousness.

11 But under 101, these are precisely the
12 sorts --

13 JUSTICE BREYER: What's your view? What's
14 your view?

15 MR. BRESS: Okay, Your Honor, I'm happy to
16 address that, too. The answer is no, and here's why.

17 JUSTICE BREYER: You should not lose it.

18 MR. BRESS: You should not lose it, and this
19 is why -- and I'll use my case as a wonderful example.

20 So, in our case, what existed before in the
21 prior art, so to speak, was people knew that you could
22 administer thiopurines for these particular diseases.
23 And, by the way, they're not all diseases; just -- we do
24 specifically exclude in these patents, for example,
25 host-versus-graft disease. We exclude leukemia, et

1 cetera. They're not in the asserted patents in this
2 case.

3 But, in any event, administration of
4 thiopurines to address certain diseases -- old in the
5 art. Different methods for finding analytes in blood
6 cells such as high-pressure liquid chromatography -- old
7 in the art, no doubt.

8 They were used together before we did them,
9 but why were they used? They were used by people who
10 were trying to come up with what we came up with. They
11 weren't doing it for fun. They were administering.
12 They were determining in order to try to find a new
13 treatment method, a new way of calibrating the right
14 dose for each individual patient based on their
15 metabolism, and help seriously ill patients.

16 And the idea that we are not novel because
17 people took some of the same steps along the way to
18 invention that we actually succeeded in is wrong. And,
19 in fact, this Court said so in *American Wood-Paper*,
20 where it said that incomplete and unsuccessful attempts
21 to invent will not render not novel the successful
22 inventor.

23 And, in *Bell*, the Court said the difference
24 between those who -- those who did not get the patents
25 and *Bell* was only the difference between failure and

1 success, and didn't say that because many of them had
2 used similar methods but had not understood that
3 continuous electrical lines as opposed to intermittent
4 or pulsing electrical lines was going to be the
5 difference for a working telephone.

6 Similar here. I don't think we ought to
7 lose on novelty for that ground. But let's put that to
8 the side, because that's for remand, and it's something
9 that, you know, hopefully, I'll get a chance --

10 JUSTICE SCALIA: Suppose somebody thinks
11 you're wrong, that the numbers you've come up with are
12 wrong. And they want to develop better numbers that
13 will -- will help the medical profession. Your patent
14 excludes them from doing that, right?

15 MR. BRESS: No, Your Honor.

16 JUSTICE SCALIA: No?

17 MR. BRESS: And let's explain why not.

18 JUSTICE SCALIA: All right.

19 MR. BRESS: And I'll even take for purposes
20 of this explanation my brother's example of over 400 and
21 under 230, because I don't think it matters. So, you've
22 got Dr. el-Azhary, who believes that the right ceiling
23 level is 300. Okay? So, if she sees a patient and
24 says, I'm going to -- you know, I associate 290 with
25 toxicity, that won't violate our patent in the least.

1 Our patent says if you associate over 400 with toxicity,
2 that's within our range. If she associates 290 with
3 toxicity, no violation.

4 Now, getting more to the point, though, if
5 we're totally wrong -- let's assume we're off base
6 and -- and this doesn't work at all. There's another
7 part of section 101 that addresses that, and that's
8 utility.

9 And, certainly, Mayo would be able to come
10 into court and say that patent has no utility. It's
11 completely wrong. In fact, it's killing patients. And
12 try to invalidate us on that ground. Similarly, suppose
13 at the very edges of the spectrums that we're claiming,
14 the answer is obvious. The answer is not novel. They
15 can seek to try to invalidate our patents on that basis
16 as well.

17 This -- these aren't 101 problems.

18 CHIEF JUSTICE ROBERTS: Well, it seems to me
19 that's your -- the problem with your whole approach is
20 that every time you're pressed on 101, your answer is to
21 fall back to 102 or 103 or the utility part of 101. And
22 I'm just wondering why it's beneficial to essentially
23 eliminate 101 and say, oh, we'll catch everything later
24 on.

25 MR. BRESS: Thank you, Mr. Chief Justice; I

1 appreciate the question.

2 I -- I think that the answer is that when
3 the problem is lack of novelty, when the problem is
4 obviousness, the right place to go are the sections that
5 actually have very clear rules on how to apply those,
6 and that the problem with taking a short cut in that
7 instance is, essentially, the court would just imbue its
8 own notions or preconceived notions of what should be
9 patentable and pour it into it as opposed to following
10 those rules.

11 And, of course, if you're going to follow
12 these rules, you might as well follow them under that
13 section. Now, it doesn't completely leave 101 bereft.
14 This Court has said 101's very broad, but it does have
15 limitations. And if you look at a case like Morse --

16 CHIEF JUSTICE ROBERTS: Well, but just to --

17 MR. BRESS: -- I think it helps explain it.

18 CHIEF JUSTICE ROBERTS: Sorry to interrupt.
19 Your friend's point is that if you don't do this -- if
20 you don't give 101 some more content, then the doctor is
21 going to have to start worrying right from the get-go
22 and then see, well, is there an exception that I might
23 be able to rely on, as opposed to being able to say
24 right away this -- I don't have to worry about this
25 patent; I can treat the patient in this way.

1 MR. BRESS: Well, Your Honor, again, if --
2 if it's very clear that we're not novel. For example,
3 if -- if the Government is correct here that facially we
4 lack novelty, it's no harder to proceed under 102 to
5 achieve that goal than it is under 101. If you're going
6 to proceed under 101, then we'll talk about principles
7 that 101 is for.

8 So, 101 -- I think the primary -- the two
9 things it's for -- it has to be a process in the
10 physical world, a hands-on process, and it can't be so
11 broad that it pre-empts all follow-on innovation. Those
12 are the two things -- you know, this Court speaks sums
13 about the statutory language, and it has to do some
14 work. That's the work that --

15 JUSTICE SOTOMAYOR: So, it's novel? What's
16 your answer about why this is novel?

17 MR. BRESS: Right. Your Honor, before
18 Prometheus -- actually, the inventors in this case in
19 Montreal came up with this method, doctors had no way to
20 tailor for each individual based on their metabolism the
21 right dosage of these powerful but potentially toxic
22 drugs.

23 CHIEF JUSTICE ROBERTS: Thank you, counsel.

24 Mr. Shapiro, you have 4 minutes remaining.

25 REBUTTAL ARGUMENT OF STEPHEN M. SHAPIRO

1 ON BEHALF OF THE PETITIONERS

2 MR. SHAPIRO: Justice Scalia asked the
3 critical question here: What if you think these numbers
4 are wrong? What happens with patients around the
5 country? Well, that's just what we concluded: These
6 numbers were wrong. They say you go up to 400, and
7 above 400, it's bad, it's harmful. We found that the
8 right range was 450 up to 700, and sometimes even above
9 700, to cure some of these very serious diseases. And
10 that different opinion was blockaded by this treble
11 damages lawsuit and request for an injunction.

12 So, the -- the wrong information is --

13 JUSTICE SCALIA: He says the solution to
14 that is -- your saying their patent is not useful.

15 MR. SHAPIRO: That it's not useful --

16 JUSTICE SCALIA: That would be your defense.

17 MR. SHAPIRO: It's important that 101 be the
18 robust test here. This is the only provision under
19 which this Court has issued decision after decision for
20 150 years protecting the public domain. It's not some
21 rough gauge; it is the critical test defining what's in
22 the storehouse of information for medical researchers to
23 use. And to reduce it to a dead letter here would be
24 just contrary to this Court's precedents and very
25 harmful to the medical community. This is very

1 important to -- to doctors around the country.

2 Now, is this a natural process? The
3 question was raised. Of course, it's a natural process.
4 These metabolites come from the liver. They don't come
5 from a test tube. They don't come from a syringe. It's
6 just like cholesterol. If I eat in a French restaurant,
7 there's some human intervention there that gives me high
8 cholesterol. And if I eat wild strawberries, there's no
9 human intervention. But either way, the doctors get to
10 look at my cholesterol and hypothesize ranges that they
11 think are sensible. It's the very same phenomenon.
12 Entirely natural.

13 Now, this is a clean legal issue. Under
14 section 101, it's always been a legal issue. They say
15 section 102 and 103 are the most elusive questions in
16 the field of patent law. This is a 7-year-old lawsuit
17 against a hospital; it's cost millions of dollars to
18 defend. Two trips to this Court, two trips to the
19 Federal Circuit. We're still litigating this treble
20 damages case. It should be terminated under this
21 Court's precedents, as the district court did giving
22 summary judgment.

23 JUSTICE SOTOMAYOR: I guess my problem is,
24 if we call this just simply an application of natural
25 phenomenon or of a natural process, why are treatment

1 patents at all --

2 MR. SHAPIRO: Well, because --

3 JUSTICE SOTOMAYOR: -- permissible, meaning
4 if someone finds out that at level 300, it's bad, and
5 tells doctors to stop, that's natural, too.

6 MR. SHAPIRO: Yes. Well, I think that's
7 right. That's -- that is a second issue. But the first
8 issue here is the breadth of the pre-emption, which
9 precludes anyone else in the country from saying, as
10 Justice Scalia did, those numbers are wrong. And
11 patients can't use those numbers safely or they won't
12 get cured of this disease. For 20 years, the public is
13 stuck with the erroneous information.

14 Now, counsel suggests that it's narrow
15 pre-emption because it doesn't cover host-versus-graft
16 or leukemia. Those are not autoimmune diseases. Every
17 autoimmune disease is swept in here. And there are
18 dozens and dozens of them. They have different
19 characteristics. You don't take a "one size fits all"
20 approach to autoimmune disease. There are different
21 numbers for different diseases.

22 That's what Mayo is trying to do, to have
23 some personalized medicine for skin disorders. And they
24 said that -- that is an infringement and we're entitled
25 to treble damages and an injunction.

1 Now, is this like the Morse case? Yes, it
2 is like the Morse case. Prometheus is trying to
3 pre-empt diseases it never researched, and it's trying
4 to pre-empt numbers that differ from its numbers
5 fundamentally.

6 They have the number 7000 in their patented
7 number. We thought the number should be 5700. This is
8 a very dangerous toxic drug. If you get the -- the
9 wrong number set in concrete for 20 years, that is a
10 huge problem for patients, and there are millions and
11 millions of patients suffering from autoimmune disease.

12 So, we urge the Court to protect the
13 research process here that's so fundamental to American
14 health and to economy and the health care industry.

15 We thank the Court.

16 CHIEF JUSTICE ROBERTS: Thank you, counsel,
17 counsel.

18 The case is submitted.

19 (Whereupon, at 11:06 a.m., the case in the
20 above-entitled matter was submitted.)

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